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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

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Memorandum

SUBJECT: Revised Occupational and Residential Exposure Assessment and Recommendations for the Risk Assessment Document for Carbendazim (MBC)

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DP Barcode:	D273465
Pesticide Chemical Codes:	MBC: 128872; Benomyl: 099101; Thiophanate-methyl: 102001
EPA Reg Nos:	Technical 5383-99.
PHED:	Yes, Version 1.1

The revised HED occupational and residential exposure risk assessment for MBC is attached. The registrant supplied comments and corrections to the June 21, 2000 version of this document and these have been incorporated. Two other exposure assessments, for thiophanate-methyl (revised - D271922) and benomyl (D264179), should be referenced due to the common metabolite (MBC). This assessment does not consider the combined or cumulative effects of exposure to different chemicals with common mechanisms of toxicity, including other inert or active ingredients in formulated products.

EXECUTIVE SUMMARY

This document contains the occupational exposure assessment for commercial and residential uses of carbendazim (methyl-2-benzimidazolecarbamate, or MBC)-containing paints and coatings and commercial tree-injection uses of MBC. The document also includes potential risk mitigation measures such as personal protective equipment (PPE) for handlers.

MBC is a fungicide used as a fungicide/preservative in paints, coatings, plaster and adhesives. MBC is formulated as a paste for commercial addition to coatings and as a capsule for loading into a tree-injection system. After commercial formulation, MBC-containing paints can be applied by brush, rollers, low-pressure hand wand and airless sprayers by professional or residential users. MBC is added to paints at a maximum concentration of 0.5 % ai (5 lbs ai/1000 lb paint) and sealants at 1.5% (15 lbs ai/1000 lb sealant).

Carbendazim is of low acute toxicity. Guideline studies for acute toxicity indicate that the carbendazim is classified as category III for acute dermal toxicity and primary eye irritation, category IV for acute oral and inhalation toxicity, and category IV for primary skin irritation. Carbendazim is not a skin sensitizer, and there is no evidence of delayed neurotoxicity in hens. The HIARC Committee on June 1, 1999 reassessed the acute and chronic dietary RfDs as well as the dermal and inhalation endpoints for occupational and residential risk assessments for benomyl, and its primary metabolite of carbendazim or MBC.[1] For short-, intermediate-, or long-term dermal exposures, a developmental NOAEL of 10 mg/kg/day for MBC was selected, based on decreased fetal body weight and increases in skeletal variations and a threshold for malformations in dams exposed to 20 mg/kg/day (LOAEL). No dermal absorption studies were located for MBC. A dermal absorption factor of 3.5 percent was selected for extrapolation from the oral dose, based on dermal absorption of benomyl. A short- and intermediate-term inhalation NOAEL of 0.96 mg/kg/day was selected based on adverse respiratory tract effects. The lung absorption factor of 100 percent is used in the calculations. Because the dermal and inhalation endpoints are based on different studies with different toxic effects, it is not appropriate to aggregate the dose via different routes of entry, e.g., oral and inhalation. A margin of exposure (MOE) greater than 100 does not exceed the Agency's level of concern for workers, while an MOE greater than 1000 does not exceed the level of concern for children and female residential handlers, as the FQPA Committee retained the 10x uncertainty factor.[2]

MBC is also classified as a Group C (possible human) carcinogen with a Q_1^* of 2.39×10^{-3} $(mg/kg/day)^{-1}$.[(3)]

It is assumed that fungicidal coating products would not be used routinely, but as needed in damp areas. Surveys of formulators and commercial painters indicate that fungicidal paint is made intermittently in batches and there is a period of days where no fungicidal batches are produced. Therefore, no continuous long-term exposures (greater than 6 months) to MBC are anticipated. Only short- (7 days or less) to intermediate-term (one week to several months) handler

exposures for formulators, arborists (for tree injection), and commercial painters are expected. Residential handlers are expected to have only short-term exposures to MBC containing compounds. Based on the low vapor pressure of MBC and the types of uses, postapplication inhalation exposure alone is anticipated as a result of treated indoor coatings, is anticipated to be far less than handler exposure. However, a high-end screening level assessment was performed for residential settings.

No chemical-specific handler exposure studies were submitted to the Agency. Surrogate data from the Pesticide Handlers Exposure Database (PHED) Version 1.1, and the Chemical Manufacturers' Association (CMA) Antimicrobial Exposure Assessment Study, were used to assess the potential exposures resulting from handling and applying MBC.[4,5] The relevant data in the PHED were obtained from an exposure study of painting bathrooms, which is a reasonable surrogate for a fungicidal paint. However, no roller painting data are available, so that exposure is assumed to be similar to paintbrush or sprayer application. Potential exposures and absorbed doses were calculated using unit exposures (i.e., normalized to amount of active ingredient handled, i.e., mg/lb ai handled) from the passive dosimetry data multiplied by the amount of MBC estimated to be handled per day (i.e., lb ai/day). The amount of MBC assumed handled per day was derived from the various application rates and the number of gallons of formulated product solution that could be applied in a single day. Dermal and inhalation margins of exposure (MOEs) are presented separately due to the different endpoints selected. Life time average daily doses (LADD) were also calculated to assess cancer risk. Exposure to other treated products, including sealants and plaster, could not be estimated as no data or applicable surrogates were available.

Of the occupational uses that could be evaluated, the inhalation exposure estimate during mixing/loading of paste and powder in the formulation process, and the ungloved dermal exposure for low-pressure handwand loader/applicators resulted in risk estimates of concern at a baseline level of protection. All other baseline risk estimates for the occupational uses of MBC (manufacturing handlers and painters with brushes or airless sprayers) did not exceed HED's level of concern for short- and intermediate-term exposures. With the addition of chemical-resistant gloves and a dust-mist respirator as controls, all of the five applicable scenarios (1a, 1b, 2, 3 and 8) had MOEs greater than 100 for the dermal and inhalation exposure routes, except the powder loading scenario (1b) which had an inhalation MOE below 100. The use of a dust/mist respirator was not effective in raising the MOE for the one inhalation scenario above 100. As an alternative to protective equipment, the use of engineering controls resulted in MOEs exceeding 1000 for the manufacturing scenarios for both exposure routes.

There were no available exposure data to evaluate exposures resulting from the tree-injection system use scenario. Due to the nature of the tree-injection system, and its use outdoors, only minimal handler exposure is anticipated via dermal or inhalation routes. The closed system of application, and the systemic nature of the treatment, indicate that handler and post-application exposures would be very low. Therefore this exposure scenario was not evaluated and the only

recommendation is that chemical-resistant gloves be worn during application. As the pesticide is incorporated into the tree tissue, a WPS restricted entry interval is not applicable.

Cancer risk estimates for the occupational scenarios for which surrogate data were available were all equal to or less than 2×10^{-5} with baseline protective clothing, and all estimates were less than 10^{-5} after addition of protective clothing, respirator, or engineering control. Engineering controls were applied, where feasible, to reduce the cancer risk estimate for handling the powdered product in manufacturing paints and coatings to less than 10^{-6}.

The short-term residential handler exposure and risk estimates are summarized in the Appendix Table A-5. There were only two scenarios for which surrogate exposure data were available: painting by brush or airless sprayer. The MOEs for residential use ranged from 230 to 9000 for inhalation, and from 620 to 750 for dermal exposure. Therefore, all dermal exposures and some inhalation exposures exceed HED's level of concern, which is an MOE of 1000 for residents. The residential cancer risk estimates were all less than 10^{-6}. There were no data available to determine exposure or risk from paint roller application or plaster and sealant application.

The vapor pressure of MBC is very low, at 7.5×10^{-10} mm Hg at 25° C, which prevents rapid off-gassing into the air. Building occupants may be exposed to the vapors of treated paint long after application. The results of the short- and intermediate-term exposure assessment, along with the cancer assessment for post-application exposures indicate that the non-occupational post-application airborne residues do not exceed HED's level of concern. The post-application MOEs for the fungicide-treated paint scenarios for toddlers and adults for inhalation exposures are 1.1×10^{6} and 4.6×10^{6}, using the Multi-chamber Concentration and Exposure Model (MCCEM) calculated air concentration. The cancer risk estimate for the same scenario is 3.6×10^{-10} for adults. These are believed to be high-end, conservative estimates. The residential handler's exposure during application would be additive to their post-application exposure.

Occupational post-application exposure to MBC-containing products would occur only intermittently, and only during working hours. Although the residential exposure would be up to several times as long as occupational exposures, the risk estimates were below the Agency's level of concern. Therefore, worker post-application inhalation exposure is also anticipated to be below the Agency's level of concern.

1.0 BACKGROUND

1.1 Purpose

In this document, which is for use in EPA's development of the Reregistration Eligibility Decision Document (RED) for carbendazim (methyl-2-benzimidazolecarbamate, or MBC), EPA presents the results of its review of the potential human health effects of occupational and residential exposure to MBC.

1.2 Criteria for Conducting Exposure Assessments

An occupational exposure assessment is required for an active ingredient if (1) certain toxicological criteria are triggered and (2) there is potential exposure to handlers (mixers, loaders, applicators, etc.) during use or to persons entering treated sites after application is complete. For MBC both criterion are met.

1.3 Summary of Toxicity Concerns

Acute Toxicology Categories

Carbendazim is of low acute toxicity. Guideline studies for acute toxicity indicate that the carbendazim is classified as category IV for acute oral and inhalation toxicity and for primary skin irritation, and category III for acute dermal toxicity and primary eye irritation. Carbendazim is not a skin sensitizer, and there is no evidence of delayed neurotoxicity in hens. Acute toxicity values and categories for carbendazim are summarized in the following table from Toxicology Chapter for the MBC RED (Smegal, 1999).[1]

Table 1
Acute Toxicity of Carbendazim

Guideline No.	Study Type	% a.i.	MRID or Accession No.	Results	Toxicity Category
870.1100 (81-1)	Acute Oral, Rat	75 INE-965	256025 (Acc No)	LD_{50} = >5000 mg/kg,	IV
870.1200 (81-2)	Acute Dermal, Rabbits	75 INE 965	256025 (Acc No)	LD_{50} = >2,000 mg/kg formulation	III
870.1300 (81-3)	Acute Inhalation, Rat	75 INE 965	256025 (Acc No)	LC_{50} >5 mg/L	IV
870.2400 (81-4)	Primary Eye Irritation, Rabbit	>98	256025 (Acc No)	minimal to no irritation	III
870.2500 (81-5)	Primary Skin Irritation, Rabbit	75 INE 965	256025 (Acc No)	slight irritation at 24 hr, normal by 72 hr	IV

Table 1 Acute Toxicity of Carbendazim					
Guideline No.	**Study Type**	**% a.i.**	**MRID or Accession No.**	**Results**	**Toxicity Category**
870.2600 (81-6)	Dermal Sensitization, Guinea Pig	98	256025 (Acc No)	not a dermal sensitizer	N/A
870.6100a (81-7)	Delayed neurotoxicity, hen	Not given	241931 (Acc No)	NOAEL = 2500 mg/kg	N/A

N/A Not applicable

Other Endpoints of Concern

Non-Cancer

The revised Hazard Identification and Assessment Review Committee (HIARC) memo, dated August 2, 1999, indicates that there are toxicological endpoints of concern for MBC. The HIARC Committee reconvened on June 1, 1999 to reassess the acute and chronic dietary RfDs as well as the dermal and inhalation endpoints for occupational and residential risk assessments for benomyl, and its primary metabolite of carbendazim or MBC. No dermal absorption, short- or intermediate-term dermal toxicity studies were located for MBC. A developmental NOAEL of 10 mg/kg/day for MBC was selected based on decreased fetal body weight and increases in skeletal variations. This is supported by a threshold for malformations in dams exposed to 20 mg/kg/day (LOAEL). The endpoints, and associated uncertainty factors, used in assessing the risks for MBC are presented in Table 2.

Table 2: Summary of Toxicological Endpoints for CARBENDAZIM (MBC)			
EXPOSURE SCENARIO	**DOSE (mg/kg/day)**	**ENDPOINT**	**STUDY**
Acute Dietary, Females 13+	NOAEL=10 UF = 100	Decreased fetal body weight and increases in skeletal variations and a threshold for malformations in Crl:CE BR strain rats	Rat Developmental Study with MBC

Table 2: Summary of Toxicological Endpoints for CARBENDAZIM (MBC)			
EXPOSURE SCENARIO	**DOSE (mg/kg/day)**	**ENDPOINT**	**STUDY**
Acute Dietary, General Population	LOAEL=50 UF = 300	Sloughing (premature release) of immature germ cells 2 days postexposure, atrophy of a few seminiferous tubules in one testicle, significant decrease in seminiferous tubule diameter, and slight abnormal growth of the efferent ductules at 70 days postexposure.	Single Dose Rat Study (Nakai et al. 1992)
MBC Acute RfD(Females 13+) =0.1 mg/kg/day MBC Acute RfD(General Population) =0.17 mg/kg/day			
Chronic Dietary	NOAEL= 2.5 UF= 100	Histopathological lesions of the liver characterized as swollen, vacuolated hepatic cells, hepatic cirrhosis and chronic hepatitis in both sexes of Beagle dogs	2 year dog study with MBC
	MBC Chronic RfD =0.025 mg/kg/day		
Short-and Intermediate Term Dermal [a]	Oral NOAEL =10 UF = 100	Decreased fetal body weight and increases in skeletal variations and a threshold for malformations in Crl:CE BR strain dams	Rat Developmental Study with MBC
Long-Term Dermal [a]	Oral NOAEL =2.5 UF = 100	Histopathological lesions of the liver characterized as swollen, vacuolated hepatic cells, hepatic cirrhosis and chronic hepatitis in both sexes of Beagle dogs	2 year dog study with MBC
Short-, Intermediate- and Long Term Inhalation	Inhalation NOAEL= 0.96 (10 mg/m^3) UF = 100 (Short & Int) UF = 300 (Long-term)	Olfactory degeneration in the nasal cavity of Sprague-Dawley rats.	90 day rat inhalation study
Cancer	Q_1* = 0.00239 (mg/kg/day)$^{-1}$	Based on hepatocellular (adenoma and/or carcinoma) tumors in CD-1 female mice. The Q_1* was estimated using the (mg/kg/day) species scaling factor.	Chronic mouse MBC studies

a = Since an oral value was selected, 3.5% dermal absorption factor should be used for route-to-route extrapolation, based on benomyl.
UF = Uncertainty Factor.

FQPA Uncertainty Factors / MOEs

For this risk assessment, HIARC determined that the 10 x factor to account for enhanced sensitivity of infants and children (as required by the Food Quality Protection Act/FQPA) should be retained.[2] Although no increased sensitivity was observed for benomyl in young rabbits following *in utero* exposure or in pups as compared to adults in the two-generation reproduction study in rats, HIARC recommends that the FQPA 10x for benomyl and MBC be retained due to increased sensitivity of rat fetuses as compared to maternal animals; concern for the developmental neurotoxic potential of Benomyl; extensive evidence from the published literature which indicates that benomyl produces CNS anomalies in rats; the evidence of neurotoxic effects in the acute and subchronic neurotoxicity (Subdivision F Guideline) studies; there is increased sensitivity of rat and rabbit fetuses as compared to maternal animals following *in utero* exposure to MBC; and there is evidence of aneuploidy induction (mutagenicity). Therefore an MOE of 1000 is appropriate for children and female residential handlers. The target MOE of 100 is appropriate for workers except for long-term inhalation where an MOE of 300 is applied due to the duration of exposure.

Because the dermal and inhalation endpoints are based on different studies with different effects, it is not appropriate to aggregate the dose to different routes of entry, e.g., oral and inhalation.

Cancer

MBC is classified as a Group C (possible human) carcinogen with a Q_1^* of 2.39×10^{-3} $(mg/kg/day)^{-1}$ based on evidence of mutagenicity.[3] In general, the Agency is concerned when occupational cancer risk estimates exceed one in ten thousand (1×10^{-4}). The Agency will seek ways to mitigate the risks, to the extent that it is practical and economically feasible, to lower the risks to one in one million (10^{-6}) or less.

1.5 Use Pattern and Formulation Summary

MBC, methyl (1H-benzimidazol-2-yl) carbamate, also known as carbendazim, is a fungicide used in a limited number of horticultural, residential, and commercial settings. All of the following manufacturing formulation and tree-injection labels were available for review. No labels for ready-to-use coatings, sealants, plaster or other commercial and residential-use products containing MBC as a fungicide were found.

Active Labels for MBC/Carbendazim

Formulation Name	Percent Active Ingredient	Product Form	EPA Registration No.
BCM Technical	99	Technical	5383-99
Mergal BCM	99	Powder	5383-100
Mergal S 89R	9.9	Paste	5383-97
Mergal S 90R	9.9	Paste	5383-98
Mergal S 89	9.9	Paste	5383-101
Mergal S 90	9.9	Paste	5383-102
Fungisol	0.3	Tree Injection	7946-14
Abasol	0.3	Tree Injection	7946-20
Imisol	0.3	Tree Injection	7946-21

MBC formulated as a fine powder (99% ai) or semi-liquid paste (9.9% ai) is incorporated in paints, coatings, plasters, and sealants in manufacturing settings using a variety of techniques. It is mixed with the product to produce a fungus- and algae-resistant product for use in warm or damp locations. There is no restriction on use location (i.e., indoor/outdoor, commercial or residential), however. MBC-containing paint is applied with handheld painting equipment (e.g., paint brush, roller, compressed-air sprayer, airless sprayer, or low-pressure hand wand). MBC is also used as an active ingredient (ai) in a tree injection formula (0.3% ai).

It is assumed that fungicidal coating products would not be used routinely, but as needed in damp areas. The Biological and Economic Assessment Division (BEAD) found no chemical-specific survey data for MBC coating use. According to Troy Chemical Co., MBC is sold only to formulators, who then produce products for both commercial and residential end-users. The vast majority of MBC sold to formulators is in the semi-liquid form as it can be pumped out of the drum and disperses more easily in the final product. Surveys of formulators and commercial painters indicate that fungicidal paint is typically made intermittently in up to 4000 gallon batches (although the registrant speculated 1000-to-2000 gallons was typical), and there is a period of days where no fungicidal batches are produced. Therefore, no long-term occupational exposures have been identified. It is considered unlikely that professional painters would spend enough time in painted areas to constitute more than short-term (less one week) dermal or inhalation exposure. Private residents would probably only use MBC-treated materials for periods less than one week at a time. However, residents with a bath or utility room painted with MBC-treated paint are likely to be exposed to vapors containing MBC for several months or more, so a long-term inhalation exposure is evaluated herein.

2.0 OCCUPATIONAL EXPOSURE AND RISK CHARACTERIZATION

An occupational and/or residential exposure assessment is required for an active ingredient if (1) certain toxicological criteria are triggered and (2) there is potential exposure to handlers (mixers, loaders, applicators, etc.) during use or to persons entering treated sites after application is complete.

2.1 Occupational Handler Exposures & Risks

HED has determined that there are potential exposures for mixers, loaders, and applicators during usual use-patterns associated with MBC. There are potential exposures from applications in commercial, industrial, and residential settings. It is assumed that exposures may be indoor or outdoor, but there are no supporting data, other than fungicides are commonly used as additives for indoor and outdoor coating and sealant materials. HED has identified two levels of handler exposures:

- primary handlers -- persons manufacturing end-use products containing MBC as an active ingredient (i.e., adding MBC to coating products)
- secondary handlers -- persons handling paint, coatings, and other products to which MBC has been added

2.1.1 Occupational Handler Exposure Scenarios: Data and Assumptions

Primary Occupational Handlers: Based on the use patterns, HED has identified two major MBC exposure scenarios for primary occupational handlers:

(1a) open-pour addition to coatings, sealants, etc. in the manufacturing process with the paste (liquid) formulation;
(1b) open-pour addition to coatings, sealants, etc. in the manufacturing process with the powder formulation.

Secondary Occupational Handlers: Based on the use patterns, HED has identified six major MBC exposure scenarios for secondary occupational handlers:

(2) applying paint/stain with a brush,
(3) applying paint/stain with an airless sprayer,
(4) applying paint/stain with a roller,
(5) applying plaster with trowel,
(6) applying caulk or other sealants,
(7) using tree fungicide injectors, and

(8) loading and applying liquid sealant with a low-pressure handwand.

Handler Exposure Data

No chemical-specific handler exposure data or studies were submitted. Data submitted by the Chemical Manufacturer's Association (CMA) for industrial mixing and loading of anti-microbials has been reviewed by Mostaghimi and Dang, and found to have too many deficiencies to use for this risk assessment.[4,5] Therefore, primary and secondary handler exposure estimates were developed using the Pesticide Handler Exposure Database (PHED) Version 1.1 surrogate data, as per Agency policy.[6] The relevant data in the PHED were obtained from open mixing/loading of liquids and wettable powder as surrogates for formulators using the flowable paste and powdered MBC. The PHED also contains exposure studies of brush and airless sprayer painting, and of low-pressure handwand spraying, which are reasonable surrogates for a fungicidal paints and coatings. However, no roller painting data are available, so that exposure is assumed to be similar to the range of exposures established for paintbrush and airless sprayer application. Short-term and intermediate-term dermal and inhalation exposures and margins of exposure (MOE) for handlers wearing a single layer of clothing are presented in Table A-1 (baseline). A single layer consists of long pants and long-sleeved shirts for painters. Table A-2 presents the dermal and inhalation risk assessments for formulators wearing gloves and respirators in addition to work clothing for formulators (as inhalation exposure from the powder formulation is contributing the lowest MOEs); loader/applicators of low-pressure handwand only need to add gloves to achieve the target MOE of 100. Table A-3 shows the result of using engineering controls: Note that there is no known water-soluble bag or closed mixing/loading system for MBC powder, but the liquid is commonly added to the formulation using a pump, according to the registrant. Tables A-4a, b, and c present the cancer risk assessment. Table A-7 summarizes the data sources, quality and confidence levels, as well as the caveats and parameters specific to each exposure scenario and corresponding risk assessment.

There are no PHED or literature data available for tree injection exposure. Note that tree injection systems (marketed by Mauget) are self-contained products that require no open mixing or direct handling of ai-containing product. A capsule is loaded into the injector and injected into the tree. Used capsules are simply disposed. The current labeling also requires coveralls, chemical-resistant gloves, chemical-resistant footwear plus socks and protective eyewear for handlers. Because of these criteria, it is the Agency's assessment that the potential exposure, and therefore the health risk of tree injection products under normal use is negligible if label use and disposal instructions are followed and chemical-resistant gloves are worn.

Note that if there are any paint/stain products containing MBC that do <u>not</u> make pesticidal claims (i.e., not registered products), then for these products HED has no regulatory authority to impose risk mitigation measures for painters. EPA can, if applicable, impose risk mitigation measures for handlers of MBC ready-to-use formulations.

Assumptions: The following assumptions are made in the exposure calculations:

- Average body weight of an adult handler is 60 kg (females 13 and older) for the short-term and intermediate-term dermal exposures as the dose was based on a developmental endpoint; a body weight of 70 kg for the long-term dermal, and all time period inhalation exposures as the doses were based on non-developmental endpoints (oral and inhalation studies, respectively); a body weight of 70 kg is used for cancer assessments as the dose is based on an oral endpoint. Therefore dermal absorbed doses were adjusted before calculating lifetime cancer risk estimates.

- Pesticide Handler Exposure Database (PHED) surrogate information is used to estimate exposure to liquids and powders while formulating and to liquid coatings treated with MBC. PHED contains data on mixer/loaders of liquids and powders and handlers applying paints and coatings by brush, airless sprayer, or low-pressure handwand.

- Data submitted by the Chemical Manufacturers Association on antimicrobial exposure, and reviewed by S. Mostaghimi of EPA, were compared to PHED data for similar scenarios. Dermal and inhalation unit exposures for workers performing the same kinds of tasks were within one order of magnitude between the two data sets. However, as stated earlier, HED chose to use PHED data because of the low number of replicates and low quality control in the CMA data, relative to PHED.

- Area treated in each scenario: paint manufacturing is assumed to prepare batches of 4,000 gallons of paint. This assumption is based on information provided by CMA and the manufacturer of MBC additives and is consistent with prior HED assessments. Commercial painters are assumed to use 5 gallons of paint per day when using a brush, or to paint the equivalent of one house per day with a sprayer. A typical house dimension is assumed to be 30 ft x 40 ft x 20 ft (2,400 ft^2 living area or 5,600 ft^2 outdoor surface area to be treated). These are considered reasonable, high-end assumptions. A commercial mixer/loader/applicator is assumed to use 40-50 gallons per day of final product. Areas painted per day or gallonage are based upon the Draft Residential SOPs, December 1997, and HED Exposure SAC Policy Number 9.[7]

- Scenarios (1a, 1b) -- open-pour applications to paints/coatings in the manufacturing process are based on reasonable high-end assumptions, using the highest rate for adding the liquid/paste and the powdered formulations. As agricultural mixing/loading surrogate data are being used, the liquid scenario is considered conservative compared to a manufacturing facility where more controlled conditions can exist. The wettable powder is used as a surrogate for the fine powder formulation, and therefore there is a fair amount of uncertainty in this assessment (i.e., the degree to which the exposure estimate under or over-estimates exposure is unknown). More specific data on this use would reduce the uncertainty. Wettable powder has been used by HED as a surrogate for other powders in previous risk assessments.

- For scenario (2), the maximum formulation rate for paint products (0.5% * 10 lb/gal for latex paint = 0.05 lb ai/gal) is used as a high-end for both paint and stains. The surrogate data for these estimates come from actual paint/stain application studies.

- The exposure data presented in scenario (3) for airless sprayers is assumed to be higher than that for compressed-air type paint/stain sprayers. Therefore, the airless sprayer is a reasonable worse-case representative for all other types of paint/stain sprayers.

- The number of treatment days per year for the cancer assessment are assumed to be as follows: 50 days for the paint manufacturing; 50 days of painting for occupational workers (use of MBC containing paint/coating once per week). These assumptions are based on the best data available to HED and AD and are consistent with other risk assessments.
- Due to a lack of scenario-specific data HED often calculates unit exposure values using generic protection factors (PF) that are applied to represent various risk mitigation options (i.e., the use of Personal Protection Equipment (PPE) and engineering controls). PPE protection factors include those representing a double layer of clothing (50 percent PF), chemical resistant gloves (90 percent PF) and respiratory protection (80 percent PF for use of a NIOSH-certified half-face dust/mist respirator type N, P, R, or HE). Engineering controls are generally assigned a PF of 98 percent.
- For short- and intermediate-term occupational exposure scenarios, an MOE of 100 (10x for intra-species and 10x for interspecies variability) is adequate. There are no anticipated long-term exposures for handlers.
- For the cancer assessment, the scenarios represent typical exposures.
- For the cancer assessment, it was also assumed that workers are exposed for 35 years over a 70 year lifetime (non-occupational exposure length is 50 years).

PHED

PHED was designed by a task force of representatives from the U.S. EPA, Health Canada, the California Department of Pesticide regulation, and member companies of the American Crop Protection Association. PHED is a software system consisting of two parts: a database of measured exposure values for workers involved in the handling of pesticides under actual field conditions and a set of computer algorithms used to subset and statistically summarize the selected data. Currently, the database contains values for over 1,700 monitored individuals (i.e., replicates). Both dermal and inhalation route exposure data are contained in the PHED.

Once the data for a given exposure scenario have been selected, the data are normalized (i.e., divided by) by the amount of pesticide handled resulting in standard unit exposures (milligrams of exposure per pound of active ingredient handled). Following normalization, the data are statistically summarized. The distribution of exposure values for each body part (e.g., chest upper arm) is categorized as normal, lognormal, or "other" (i.e., neither normal nor lognormal). A central tendency value is then selected from the distribution of the exposure values for each

body part. These values are the arithmetic mean for normal distributions, the geometric mean for lognormal distributions, and the median for all "other" distributions. Once selected, the central tendency values for each body part are composited into a "best fit" exposure value representing the entire body.

The unit exposure values calculated by PHED generally range from the geometric mean to the median of the selected data set. To add consistency and quality control to the values produced from this system, the PHED Task Force has evaluated all data within the system and has developed a set of grading criteria to characterize the quality of the original study data. The assessment of data quality is based on the number of observations and the available quality control data. These evaluation criteria and the caveats specific to each exposure scenario are summarized in Table A-7 in the Appendix. While data from PHED provide the best available information on handler exposures, it should be noted that some aspects of the included studies (e.g., duration, acres treated, pounds of active ingredient handled) may not accurately represent labeled uses in all cases. HED has developed a series of tables of standard unit exposure values for many occupational scenarios that can be utilized to ensure consistency in exposure assessments.

Exposure Calculations: The following calculations are used to assess the risk to handlers.

Daily Exposure (mg ai/day) is calculated using the following equation:

$$\text{Daily Dermal Exposure}\left(\frac{\text{mg ai}}{\text{day}}\right) = \text{Unit Exposure}\left(\frac{\text{mg ai}}{\text{lb ai}}\right) * \text{Rate}\left(\frac{\text{lb ai}}{\text{Gallon}}\right) * \text{Daily Treated}\left(\frac{\text{Gallons}}{\text{day}}\right)$$

Where:

Daily Dermal Exposure = Amount deposited on the surface of the skin that is available for dermal absorption, also referred to as potential dose *(mg ai/day)*;
Unit Exposure = Normalized exposure value derived from August, 1998 PHED Surrogate Exposure Table, as no chemical-specific handler data were available for this assessment (mg ai/pound ai applied);
Use Rate = Normalized application rate based on a logical unit treatment such as gallons, a practical maximum value is generally used *(lb ai/gallon)* for each scenario; and
Daily Quantity Treated = Normalized application area based on a logical unit treatment such as gallons (Gal/day).

Daily inhalation exposures were calculated using the following:

$$\text{Daily Inhalation Exposure}\left(\frac{\text{mg ai}}{\text{day}}\right) = \text{Unit Exposure}\left(\frac{\text{ug ai}}{\text{lb ai}}\right) * \frac{1\text{ mg}}{1000\text{ ug}} * \text{Rate}\left(\frac{\text{lb ai}}{\text{gallon}}\right) * \text{Daily Treated}\left(\frac{\text{Gallons}}{\text{day}}\right)$$

Where:

Daily Inhalation Exposure = amount that is available for absorption, also referred to as potential dose (mg ai/day);
Unit Exposure = Normalized exposure value derived from August, 1998 PHED Surrogate Exposure Table, no chemical-specific handler data were available for this assessment (mg ai/pound ai applied);
Use Rate = Normalized application rate based on a logical unit treatment such as gallons, a maximum value is generally used (lb ai/Gal); and
Daily Quantity Treated = Normalized application area based on a logical unit treatment such as Gallons(Gal/day).

Absorbed Daily Dose due to Dermal Exposure (mg/kg/day) is calculated using the following formula:

$$\textit{Absorbed Daily Dose}\left(\frac{\textit{mg AI}}{\textit{Kg Day}}\right) = \textit{Daily Exposure}\left(\frac{\textit{mg AI}}{\textit{Day}}\right) \cdot \left(\frac{1}{\textit{Body Weight (Kg)}}\right) \cdot \textit{Dermal Absorption}$$

A dermal absorption rate of 3.5 percent was used for short- and intermediate-term, and cancer dermal hazard assessment. For inhalation exposure, an absorption rate of 100 percent is assumed.

As stated in Section 1.3, the dermal and inhalation endpoints are based on different studies with different toxic effects, and therefore it is not appropriate to aggregate the dose to different routes of entry, e.g., oral and inhalation.

Short-Term and Intermediate-Term Non-Cancer Risk/Margin of Exposure (MOE) were calculated separately for each route of exposure using the following formula:

$$MOE = \frac{NOAEL\left(\frac{mg}{kg\ day}\right)}{\textit{Absorbed Daily Dose}\left(\frac{mg}{kg\ day}\right)}$$

The lifetime average daily dose (LADD) is a measure of the lifetime exposure for the purpose of estimating cancer risk. The LADD is calculated using the following formula:

$$\textit{LADD (mg/kg/day)} = \textit{Daily Total Dose (mg/kg/day)} * \left(\frac{\textit{Days Worked}}{\textit{365Days/Year}}\right) * \left(\frac{\textit{35 Years Worked}}{\textit{70 Year Lifetime}}\right)$$

where: *Daily Total Dose (mg/kg/day) = Daily Absorbed Dermal Dose (mg/kg/day) + Daily Inhalation Dose (mg/kg/day)*

The estimated cancer risk is calculated using the following formula:

$$Estimated\ Risk = LADD\ (mg/kg/day) * Q_1^*\ (mg/kg/day)^{-1}$$

2.1.3 Handler Exposure and Non-Cancer Risk Estimates

Dermal Risk Estimate

Short-term and Intermediate-term (from Table A-1)

The calculations of short-term and intermediate-term dermal exposure indicate that the MOEs are more than 100, and therefore do not exceed the level of concern at **baseline** (including gloves for mixer/loaders) for four of the five scenarios for which data are available:

- (1a) adding paste formulations to paint in the manufacturing process;
- (1b) adding powdered formulation to paint in the manufacturing process;
- (2) applying ready-to-use paint/stain formulation with a brush;
- (3) applying ready-to-use paint/stain formulation with airless sprayer;

Only one scenario had a risk that exceeded the level of concern (MOE = 69):

- (8) mixing/loading/applying ready-to-use paint/stain formulation with a low-pressure hand wand.

Inhalation Risk Estimate (Table A-1)

The calculations of short and intermediate term inhalation exposure indicate that the MOEs are more than 100 at **baseline** (no respirator) (Table A-1) for the following scenarios:

- (1a) mixing/loading liquid (paste) formulation to paint/coatings in the manufacturing process;
- (2) applying ready-to-use formulations and paint products with a paint brush;
- (3) applying ready-to-use paint/coating formulation with an airless sprayer;
- (8) mixing/loading/applying ready-to-use paint/stain formulation with a low-pressure hand wand.

The calculations of short-term and intermediate-term inhalation exposure indicate that the MOE remains less than 100 even with **the addition of a dust/mist respirator** (Table A-2) for the following scenario:

- (1b) adding powdered formulation to paint in the manufacturing process.

With engineering controls (Table A-3: based on PHED data), in the manufacturing scenarios, both of the mixer/loader scenarios had MOEs greater than 100, in fact, all MOEs were greater than 1000. No data were available to evaluate engineering controls for any other exposure scenarios. The practicality of using water-soluble bags for powdered formulation is unknown at this time.

2.1.4 Cancer Risk Estimates (Tables A-4a,b,c)

The calculations of total (dermal + inhalation) cancer risk indicate that the estimated risks are between 1×10^{-5} and 1×10^{-7} at **baseline** for all handler scenarios that could be evaluated:

- (1a) adding paste formulations to paint at the manufacturing process;
- (1b) adding powdered formulation to paint at the manufacturing process;
- (2) applying ready-to-use paint/stain formulation with a brush.
- (3) applying ready-to-use paint/stain formulation with airless sprayer

The calculations of total cancer risk indicate that the estimated risks are between 1×10^{-5} and 1×10^{-7} with **additional personal protective equipment** for all handler scenarios for which data are available.

The calculations of total cancer risk indicate that the estimated risks are less than 1×10^{-6} with the **addition of engineering controls** for handler scenarios (1a & 1b); no data are available to evaluate the hand-held applications (i.e., not considered feasible at this time).

2.1.5 Level of Confidence, Data Gaps, and Summary of Handler Risks

The levels of confidence in the PHED and CMA study data are summarized in the Table A-7. There are data gaps for the following scenarios:

- (4) applying ready-to-use paint with a paint roller;
- (5) applying other ready-to-use plaster formulation with trowel;
- (6) applying ready-to-use sealant formulation by hand;
- (7) handling and applying tree injection systems.

Although no quantitative assessment is possible at this time for scenarios 4-6, it is anticipated that exposure and risk levels will not exceed those of a brush painter alone. In scenarios 4-6, moderate to high skin contact is likely, but the daily quantity of active ingredient handled is not expected to exceed the quantity handled by painters. As stated earlier, scenario 7 is unlikely to

result in significant exposure when used as directed on the label, and therefore was not addressed quantitatively in this risk assessment.

Currently, there is no information available on the use of closed systems in the formulation process. Such information would help to refine the current risk estimates.

Summary of Occupational Handler Risks

Only the inhalation exposure during mixing/loading of powder in the formulation process (scenario 1b) produced a risk estimate of concern at a baseline level of protection. All other baseline risk estimates for the occupational uses of MBC (manufacturing handlers and painters with brushes, airless sprayers, or low-pressure hand wands) were below HED's level of concern for short- and intermediate-term exposures (baseline range: dermal MOEs 380-9,300; inhalation MOEs 8-900). The addition of a dust-mist respirator as a control method did not raise the inhalation MOE above 100 for loading the dust (glove plus respirator range: dermal MOEs 500-9300; inhalation MOEs 39-3500). Although not currently available for the dust formulation, the use of a water-soluble bag as an engineering control elevated the inhalation MOE above 1000 for the manufacturing scenario (engineering controls range: dermal MOEs 3600-10,000; inhalation MOEs 3600-10,000.

Cancer risk estimates for the scenarios for which data were available were all less than 10^{-5} with baseline protective clothing, and four of five estimates were less than 10^{-6} with the addition of a dust/mist respirator or engineering controls.

There are four use scenarios for which no data have been submitted and no data are available: Applying ready-to-use tree injection, paint roller, plaster, and sealant. However, the uses for which there are data gaps are all anticipated to cause dermal and inhalation exposures within the range of the brush or spray painting scenarios.

2.2 Occupational Postapplication Exposure & Risk Estimates

Commercial Handlers of Ready-to-Use MBC-Treated Coatings and Materials

Post-application occupational exposure to MBC-containing coatings and materials would be primarily by inhalation, as dermal contact would be avoided until the treated material (paint, sealant, plaster) had dried or "cured." After drying, no dermal exposure is expected from MBC-treated materials even with incidental direct contact. Products with MBC are generally used only in damp locations where a fungicide is required, and are therefore not used routinely. Handlers of MBC or MBC-treated materials are anticipated to have a greater exposure to MBC than any post-application occupationally-exposed group. Given the uncertainty and lack of information about post-application exposure to MBC, it is assumed that the handler risk estimates represent the high-end for possible occupational post-application exposure. Because the activities causing

exposure are intermittent, and no post-application inhalation monitoring data are available for the use of MBC-containing products, an accurate quantitative risk estimate is not feasible for occupational uses. Qualitatively, a very low potential exposure is expected based on the low MBC vapor pressure of 7.5×10^{-10} mm Hg at 25° C and the small amount of active ingredient in the ready-to-use product (maximum 1.5%).

The brush applicator inhalation exposure potential to these products, which is experienced by commercial painters using MBC-containing paints and coatings results in exposure and risk estimates of MOEs >100 for commercial painters and MOEs > 300 for residential painters) at baseline (i.e., without the use of a respirator). Occupational post-application inhalation exposures are expected to be substantially lower than those experienced by occupational handlers, due to the low vapor pressure and the matrix effects of the parent vehicle which will hinder volatilization. Although MOEs for spraying paint are less than 100, this exposure would far exceed any potential post-application exposure. The Agency does not anticipate that commercial handlers of ready-to-use product would remain in rooms that have been freshly painted for any extent of time. To what extent bystanders, such as building contractors, might be exposed to MBC in paint vapors is purely speculative given the lack of information. It is unlikely, however, that secondary (passive) exposure to MBC-containing vapors will result in exposure risks of concern based on the calculated handler inhalation risks, the low calculated resident inhalation risk, and the low vapor pressure of MBC.

While occupational post-application exposure to MBC-containing products would occur only intermittently, and only during working hours, residents would potentially be exposed for longer periods of time, and therefore potentially receive a higher dose. In section 3.2, the Multi-chamber Concentration and Exposure Model (MCCEM) is used to estimate residents' post-application inhalation exposure to MBC-paints. Although the residential exposure would be up to several times as long as occupational exposures, the risk estimates were below the Agency's level of concern. Therefore, worker post-application inhalation exposure is also anticipated to be below the Agency's level of concern.

Formulators of MBC-Containing Products

The post-formulation exposure to MBC via inhalation is anticipated to be very low for the reasons cited above. However, occupational and incidental (bystander) inhalation exposure to MBC should be limited by use of engineering controls (e.g., closed mixing and loading, local exhaust ventilation) in the formulation setting. The efficacy of controls should be evaluated by air monitoring.

Tree-Injection Uses

HED has determined that there is negligible potential post-application exposure to MBC following injection application to trees, based on the use of a closed system, outdoor use, small quantities, and the tissue-incorporation of the product, preventing its release.

2.3 Occupational Risk Characterization & Recommendations

Handler Studies

There are no data available for three categories of the registered uses of MBC; applying ready-to-use formulations with a paint roller, hand application of plaster and sealants, and tree injection.

Applying ready-to-use formulations with a paint roller is not believed to present a greater exposure or risk than that from that from using a paint brush (worst case dermal), or from using an airless sprayer (worst case inhalation); both of which have been determined to have MOEs equal to or greater than the target MOE. However, there is no known method to estimate the exposure due to hand application of sealants, plasters, etc., treated with MBC. Therefore, handler exposure data are needed to accurately characterize this form of application. See Series 875 Group A for study materials and methods.

Additionally, HED requests use information, such as typical use pattern, method(s) of application, and frequency and duration of potential exposure for the sealant, plaster, and other material uses if, indeed such uses exist. There are no labels available showing MBC use in plaster and sealants, although the formulators' labels allow such use.

Postapplication Studies

Although modeling based on physical and chemical properties of MBC predicts low post-application airborne concentrations, there are no actual data. Therefore, it is recommended that a *small chamber test* be conducted with actual paint formulated to label specifications (i.e., 0.5% ai) to verify airborne concentrations are below the level of concern. A single test may be used for documentation of both occupational and residential post-application exposure.

3.0 RESIDENTIAL AND OTHER NON-OCCUPATIONAL EXPOSURES AND RISK ESTIMATES

3.1 Residential Handler Exposures and Risk Estimates

This assessment reflects the Agency's current approaches for completing residential exposure assessments based on the guidance provided in the *Draft: Series 875-Occupational and Residential Exposure Test Guidelines, Group B-Postapplication Exposure Monitoring Test Guidelines*, the *Draft: Standard Operating Procedures (SOPs) for Residential Exposure Assessment*, and the *Overview of Issues Related to the Standard Operating Procedures for Residential Exposure Assessment* presented at the September 1999 meeting of the FIFRA Scientific Advisory Panel (SAP).[7,8,9] The Agency is, however, currently in the process of revising its guidance for completing these types of assessments. Modifications to this assessment shall be

incorporated as updated guidance becomes available. This will include expanding the scope of the residential exposure assessments by developing guidance for characterizing exposures from other sources already not addressed such as from spray drift; residential residue track-in; exposures to farm worker children; and exposures to children in schools.

3.1.1 Residential Handler Exposure Scenarios, Data, and Assumptions

Exposure Scenarios:

Based on the use patterns, HED has identified six major MBC exposure scenarios for residential handlers of ready-to-use products:

(1) applying paint/coating with a brush,
(2) applying paint/coating with an airless sprayer,
(3) applying paint with a roller,
(4) applying plaster formulation with a trowel,
(5) applying ready-to use sealant formulation by hand, and
(6) applying ready-to-use paint/coating using a low-pressure hand wand.

Residential handlers are anticipated to have only short-term (one week or less) dermal and inhalation exposures to MBC as a fungicidal additive in ready-to-use products (see assumptions below). The formulation is not labeled for consumers to add on-site, but only for manufacturing in 1000 lb lots. Although several tree-injection products are manufactured containing MBC, all labels specifically restrict use to trained professionals.

Assumptions:

The same assumptions apply for residential-applicators as for occupational handlers of ready-mixed fungicidal coatings, except the amounts used are lower. Residential assumptions are as follows:

- Application rate: 2 gallons of paint or coating per day. For cancer risk estimates, residential applicators are anticipated to apply paint or coatings 4 days per year (Draft SOPs for Residential Exposure Assessments 12/97).
- Typical homeowner clothing indoors is represented by short pants, short sleeve shirt, no gloves; these are also the clothing assumed in the Draft SOPs for Residential Exposure Assessments, 12/97.
- The concentration of ai/gallon and the potential exposure rate were calculated as follows:

It is assumed that the paint density is 10 lb/gallon. Based on maximum label concentration of 0.5%,

- 10 lb/gal x 0.5% ai = 0.05 lb ai/gal x 2.5 gal/1,000 ft2 typical application rate = 0.125 lb/1000 ft2;

- Exposure (mg/day) = Unit exposure (mg/lb ai) * Appl. rate (lb ai/gal or lb/ft2) * gallons or square feet treated;
- Absorbed daily dose [dermal] = Exposure * dermal absorption factor (3.5%) / body weight (60 kg for developmental endpoint);
- Daily inhalation exposure (mg/day) = [Unit exposure (µg/lb ai)/1,000 µg/mg conversion] * Appl. rate (lb ai/gal or lb/ft2) * gallons or square feet treated;
- Absorbed daily dose [inhalation] = Exposure * inhalation absorption factor (100%) / body weight (70 kg for developmental endpoint).

$$MOE = \frac{NOAEL\left(\frac{mg}{kg\ day}\right)}{Absorbed\ Daily\ Dose\left(\frac{mg}{kg\ day}\right)}$$

Data:

There were no chemical-specific handler exposure data available for MBC users, therefore surrogate data were obtained from the Draft SOPs for Residential Exposure Assessments, December 1997. These values were specific for residential users wearing short-sleeved shirts and short pants and no gloves.

3.1.2 Residential Handler Exposure and Non-Cancer Risk Estimates

All of the dermal and some inhalation MOEs for short-term exposures failed to meet the target MOE of 1000 for non-occupational handlers. The residential handler exposure and risk estimates are summarized in the Appendix Table A-5. The dermal MOE was 750 for applying paints and coatings with a paint brush and the inhalation MOE was 2400. For painting with an airless sprayer, the risks estimates were greater, i.e., the dermal MOE was 620 and the inhalation MOE was 230. Loading and applying 5 gallons of liquid with a low-pressure hand wand resulted in a dermal MOE of 690 and an inhalation MOE of 9000. There were no data available to determine exposure or risk from paint roller application or plaster and sealant application.

3.1.3. Residential Handler Exposure and Risk Estimates for Cancer

Cancer risk estimates were calculated in the same manner as for occupational handler exposure, using the same formulae but incorporating the assumptions in Section 3.1.1 above for quantity and days painting per year (Table A-6). Surrogate PHED data for paintbrush and airless sprayer application were available .

The dermal cancer risk estimate for residential applicators brush painting with treated product was 2.1×10^{-7}, the inhalation cancer risk estimate was 7.6×10^{-9} , and the total cancer risk estimate was 2.2×10^{-7}. Using an airless sprayer to apply paint and coatings resulted in a dermal cancer risk estimate of 6.4×10^{-8}, an inhalation cancer risk of 1.9×10^{-8} , and a total

cancer risk estimate of 8.4×10^{-8}. Applying five treated gallons with a low-pressure hand wand each year resulted in a dermal cancer risk estimate of 5.9×10^{-8}, an inhalation cancer risk of 5.2×10^{-10}, and a total cancer risk estimate of 6.0×10^{-8}. There are no data available to evaluate cancer risks for use of MBC treated paints with a roller, or in a sealant compound.

3.1.4 Summary of Risk Concerns for Residential-Handlers, Data Gaps, and Confidence in Exposure and Risk Estimates

There were three scenarios for which surrogate exposure data were available: painting by brush or airless sprayer, and low-pressure handwand spraying. The MOEs ranged from 230 to 9000 for inhalation, and from 620 to 750 for dermal exposure. Therefore most non-cancer risks failed to meet the target MOE. However, the cancer risk estimates were less than 10^{-6}.

Although there were no chemical-specific data for any of the handler scenarios, the available PHED data was taken from painting studies believed to be relatively similar to the three assessed scenarios. Also, the surrogate data were of medium-to-high confidence level.

3.2 Non-Occupational Post-application Exposures and Risks

3.2.1 Post-application Exposure Scenarios, Data, and Assumptions

Post-application exposure to MBC-treated paints, coatings, and sealants is anticipated to be only by the inhalation route, as the treated materials will have dried and be relatively inert. It is anticipated that, qualitatively, only very low exposures to MBC would be obtained from inhalation of vapors in a treated room, due to the inhalation MOE of 2400 for a residential brush-painting 2 gallons of paint, and also owing to the very low vapor pressure of MBC. However, a quantitative assessment of potential inhalation exposure was conducted by using modeling the emission rate of the active ingredient from the product. The models used are described in the Draft Residential SOPs, Section 13.2.

MCCEM

The Multi-Chamber Concentration and Exposure Model (MCCEM), as outlined in the SOPs for Residential Exposure Assessments (12/18/97), was used to estimate post application inhalation exposures for occupants after painting one room (2 gallons of paint) in a home.(MCCEM is on the Internet at: http://www.epa.gov/opptintr/exposure/docs/mccem.htm). [10] The model-estimated air concentration in the remainder of the house for one year following the painting of a bathroom was used to determine occupant exposure. The following assumptions and considerations were used:

- Adults are assumed to weigh 70 kg. Toddlers (3 years old), used to represent the 1 to 6 year old age group, are assumed to weigh 15 kg.

- A mean inhalation rate of 13.3 m^3/day for all adults and 8.7 m^3/day for children 3-6 years old were used to calculate daily exposures (policy: Draft Residential SOPs, 1997; data from the Exposure Factors Handbook, August 1997.

- Adults are assumed to reside in the home 16.4 hours/day, while children are assumed to spend 21 hours per day in the home (Exposure Factors Handbook, August 1997).

- Because the MBC is mixed into a paint, there are matrix effects caused by the latex or other vehicle which may act to slow the volatilization of the active ingredient.

- The generic house model was used in the MCCEM run. There are 2 zones in the model, the painted room (i.e., bath) and the remainder of the house. The residents are assumed to spend most of their time in the rest of the house.

- All of the paint applied is considered a potential source for airborne contaminants in a Chinn type emission.[11] No decay or reaction with other chemicals was calculated, but air exchanges are considered. The maximum concentration in paints per label instructions is 0.5% (sealants may contain up to 1.5% ai but there are no data on use patterns or exposures, and paints are commonly used in much greater quantity than sealants.

The inputs used for the MCCEM run are summarized in Table A-8.

Chinn Release Emission Rate Calculations:

er = m/d

er = emission rate in grams/hr

m = mass of ai in grams

$d = 145 / ((MW*VP)^{0.9546})$

d = Chinn evaporation time (hrs)

MW = molecular weight of ai

vp = Vapor Pressure of ai

m = (10 lbs paint/gal)* (454 g/lb) * (0.5% max ai) * 2 gal/day = 45.4 gm

d = 145/(360.5 g/mole)*$(7.5 \times 10^{-10}$ torr$)^{0.9546}$ = 2.1×10^8 hrs

er = 45.4g/2.1×10^8 hr = 2.2×10^{-7} g/hr

The results of the 2-zone MCCEM run using the above emission rate for a period of one year were:

TWA in room 1 (painted bathroom) = 5.06×10^{-6} mg/m^3

TWA in room 2 (remainder of house) = 1.69×10^{-6} mg/m^3
ADD and MOE Calculations:

ADD = $(C_a * IR)/BW$

ADD = Average Daily Dose (mg/kg/day)
C_a = MCCEM modeled airborne concentration of pesticide in air (1.69×10^{-6} mg/m^3)
IR = inhalation rate (m^3/day)
BW = body weight (kg)

3.2.2 Non-Cancer Risk Estimates:

Toddlers: **ADD** = $(1.69 \times 10^{-6}$ mg/m^3)x(8.7 m^3/day)/15 kg x (21/24 hr/day) = **8.6×10^{-7} mg/kg/day**

MOE = $\frac{NOAEL_{Inhalation}}{ADD} = \frac{0.96 \text{ mg/kg/day}}{8.6 \times 10^{-6} \text{ mg/kg/day}} = 1.1 \times 10^6$

Adults: **ADD** = $(1.69 \times 10^{-6}$ mg/m^3)x(13.3 m^3/day)/70 kg x (16/24 hr/day) = **2.1×10^{-7} mg/kg/day**

MOE = $\frac{NOAEL}{ADD} = \frac{0.96 \text{ mg/kg/day}}{2.1 \times 10^{-7} \text{ mg/kg/day}} = 4.6 \times 10^6$

3.2.3 Cancer Risk Estimates:

Cancer Risk Estimate = LADD x $[Q_1^* (0.00239 \text{ mg/kg/day})^{-1}]$
LADD = ADD x 50 yrs exposure / 70 year lifetime (assuming daily exposure)
Adult = $[2.1 \times 10^{-7}$ mg/kg/day x 50/70 yrs] x $(0.00239 \text{ mg/kg/day})^{-1}$ = **3.6×10^{-10}**

This estimate uses the maximum air concentration predicted by MCCEM and assumes exposure every day for 50 years. Therefore this is considered a conservative, or high-end cancer risk estimate.

3.2.4 Summary of Residential Post-Application Risks, Data Gaps, and Confidence in Exposure and Risk Estimates:

The inhalation treated paint scenario post-application MOEs for toddlers and adults are 1.1×10^6 and 4.6×10^6 respectively, using the MCCEM calculated air concentration. The cancer risk estimates for the same scenario are 3.6×10^{-10} for adults. These are believed to be high-end, conservative estimates.

This scenario and the risk estimates would be the same for passively exposed occupants, whether painted by professional or occupant. The occupant's exposure during application, described in Section 3.1, would be additive to their post-application exposure, yielding a total cancer risk well below the Agency's level of concern of one in one million.

The post-application non-cancer and cancer risk estimates were based upon the Residential SOPs and modeling using the MCCEM. While the Residential SOPs combine median values for population attributes with conservative assumptions, the MCCEM estimate is characterized as high-end because the generic house option was selected per the Residential SOPs. Users are unlikely to repaint the same rooms annually as in the model, nor will they be exposed 365 days per year. Also, MBC has a very low vapor pressure and MBC-containing products are only intended for use in damp areas such as bathrooms or basements. Therefore, although there is no chemical-specific data available for this chemical, the most conservative assessment indicates exposures will not create risks of concern.

References

1. Smegal, D. Memo to J. Rowland. Benomyl and Carbendazim - Re-evaluation - Report of the Hazard Identification Assessment Review Committee. U.S. EPA. August 2, 1999.
2. Tarplee, B., et al. BENOMYL - Report of the FQPA Safety Factor Committee. U.S. EPA. July 1, 1999.
3. Brunsman, L. Memo to D. Smegal. Revised Benomyl/MBC Quantitative Risk Assessment (Q_1*) Based on CD-1 Mouse Dietary Study Using mg/kg b.s. 3/4's /day Cross Species Scaling Factor. U.S. EPA. November 18, 1999.
4. MRID 425875-01 Popendorf, et al. Chemical Manufacturers Association Antimicrobial Exposure Assessment Study. University of Iowa. December 8, 1992.
5. Mostaghimi, S. Memorandum to Fairfax, J. Evaluation of Chemical Manufacturers Association Antimicrobial Exposure Assessment Study. U.S. EPA. November 4, 1999.
6. Keigwin, T. PHED Surrogate Exposure Guide. U.S. EPA. August 1998.
7. [Draft] OPPTS Series 875-Occupational and Residential Test Guidelines: Group B-Postapplication Exposure Monitoring Test Guidelines. EPA. February 1998 version.
8. Draft SOPs for Residential Exposure Assessments. EPA. December 18, 1997.
9. Overview of Issues Related to the Standard Operating Procedures for Residential Exposure Assessment presented at the September 1999 meeting of the FIFRA Scientific Advisory Panel (SAP). EPA. August 5, 1999.
10. Multi-chamber Concentration and Exposure Model (MCCEM): User's Guide, version 2.4. Office of Pollution Prevention and Toxics, Economics, Exposure and Technology Division, Exposure Assessment Branch. U.S. EPA. 1995.
11. Chinn, K. A simple method for predicting chemical agent evaporation. September 1981. Dugway, UT: U.S. Army Proving Ground. DPG Document No. DPG-TR-401.

APPENDIX

Handler Exposure/Risk Assessment

Tables A-1 Through A-8

Table A-1: Occupational MBC Handler: Baseline Short-term and Intermediate-term Dermal and Inhalation Exposures and Risk Estimates

Exposure Scenario (Scenario #)	Baseline Dermal Unit Exposure (mg/lb ai)[a]	Baseline Inhalation Unit Exposure (µg/lb ai)	Application Rate[b]	Amount Handled[c]	Absorbed Daily Dermal Exposure (mg/kg/day)[d]	Daily Inhalation Exposure (mg/kg/day)[e]	Dermal MOE[f]	Inhalation MOE[g]
Mixer/Loader Exposure								
Adding Paste Formulation (9.9% ai) to Paint at the Manufacturing Process (1a)	0.023	1.2	0.02 lb ai/gallon	4,000 gallons of Paint	1.1E-03	1.4E-03	9300	700
Adding Powdered Formulation (99% ai) to Paint at the Manufacturing Process (1b)	0.17	43	0.05 lb ai/gallon		0.020	0.12	500	8
Applicator Exposure								
Applying Ready-to-use Paint/Coating Product with a Paint Brush (2)	180	280	0.05 lb ai/gallon	5 gallons	0.026	0.001	380	960
Applying Ready-to-Use Paint/Coating Product with an Airless Sprayer (3)	38	830	0.125 lb ai/1,000 ft^2	5,600 ft^2	0.016	8.3E-03	640	120
Applying Ready-to-use Paint/Coating Product with a Paint Roller (4)	No Data	No Data	0.05 lb ai/gallon	No Data	No Data	No Data	No Data	No Data
Applying Ready-to-use Plaster Formulation with a Trowel (5)	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data
Applying Ready-to-use Sealant Formulation by Hand (6)	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data
Applying Tree Injection (7)	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data
Loading/Applying Ready-to-use Paint/Coating Product with a Low-Pressure Handwand (8)	100	30	0.05	50	0.15	0.0011	69	900

[a] Baseline dermal unit exposure represents long pants, long sleeved shirt, no gloves (except 1a & 1b), open mixing/loading.

[b] Based on maximum final concentration 0.5% for 99% formulation label, and 0.2% for 9.9% formulation label; it is assumed that the paint density is 10 lb/gallon (the same as the formulation). Therefore 10 lb/gal x 0.5% ai = 0.05 lb ai/gal x 2.5 gal/1,000 ft^2 typical application rate = 0.125 lb/1000 ft^2; assumed house size of 30 ft x 40 ft x 20 ft (2,400 ft^2 living area and 2,800 ft^2 outdoor surface area treated x 2 houses/day).

[c] Daily gallons of paint/stain handled are from the EPA estimates of gallonage that could be used in a single day for each exposure scenario of concern.

[d] Daily dermal exposure (mg/day) = Unit exposure (mg/lb ai) * Appl. rate (lb ai/gal or lb/ft^2) * Gallons or square feet treated.
Absorbed daily dose [dermal] = Exposure * dermal absorption factor (3.5%) / body weight (60 kg for developmental endpoint).

[e] Daily inhalation exposure (mg/day) = [Unit exposure (µg/lb ai)/1,000 µg/mg conversion] * Appl. rate (lb ai/gal or lb/ft^2) * Gallons or square feet treated.
Absorbed daily dose [inhalation] = Exposure * absorption factor (100%) / body weight (70 kg for olfactory degeneration endpoint).

[f] MOE [dermal] = NOAEL $_{dermal}$ (10 mg/kg/day) / Absorbed daily dermal dose (mg/kg/day); target MOE = 100

[g] MOE [inhalation] = NOAEL $_{inhalation}$ (0.96 mg/kg/day) / Absorbed daily inhalation dose (mg/kg/day); Target MOE = 300

"No data" scenarios: refer to Section 2.1.3, "Data Gaps"

Table A-2: Occupational MBC Handler: Mitigation: Chemical-Resistant Gloves and Dust/Mist Respirator: Short-term and Intermediate-term Dermal and Inhalation Exposure and Risk Estimates

Exposure Scenario (Scenario #)	PPE Dermal Unit Exposure (mg/lb ai)[a]	Dust/Mist Respirator Inhalation Unit Exposure (µg/lb ai)[b]	Application Rate[c]	Amount Handled[d]	Absorbed Dermal Dose (mg/kg/day)[e]	Inhalation Dose (mg/kg/day)[f]	Dermal MOE[g]	Inhalation MOE[h]
Mixer/Loader Exposure								
Adding Paste Formulation (9.9% ai) to Paint at the Manufacturing Process (1a)	0.023	0.24	0.02 lb ai/gallon	4,000 gallons of Paint	1.1E-03	2.7E-04	9300	3500
Adding Powdered Formulation (99% ai) to Paint at the Manufacturing Process (1b)	0.17	8.7	0.05 lb ai/gallon		0.020	0.025	500	39
Applicator Exposure								
Applying Paint/Coating Product with a Paint Brush (2)	NE	NE	0.05 lb ai/gallon	5 gallons	NE	NE	NE	NE
Applying Paint/Coating Formulation with an Airless Sprayer (3)	NE	NE	0.125 lb ai/1,000 ft^2	5,600 ft^2 (2.1 lb ai)	NE	NE	NE	NE
Mixer/Loader/Applicator								
Mixing/Loading/Applying Ready-to-use Paint/Coating Product with a Low-Pressure Handwand (8)	0.43	30	0.05	50	6.3E-04	1.1E-03	1.6E+04	900

Numbers in table were calculated using spreadsheet and rounded to two significant figures.
NE = Scenario not evaluated as target MOE exceeded at baseline PPE.

[a] Dermal unit exposure represents long pants and long sleeved shirt; chemical resistant gloves;

[b] Inhalation unit exposure based on use of dust/mist respirator (80% PF) except no respirator required for scenario (8); all open mixing/loading.

[c] Based on maximum final concentration 0.5% for 99% formulation label, and 0.2% for 9.9% formulation label; it is assumed that the paint density is 10 lb/gallon (the same as the formulation). Therefore 10 lb/gal x 0.5% ai = 0.05 lb ai/gal x 2.5 gal/1,000 ft^2 typical application rate = 0.125 lb/1000 ft^2; assumed house size of 30 ft x 40 ft x 20 ft (2,400 ft^2 living area and 2,800 ft^2 outdoor surface area treated x 2 houses/day).

[d] Daily gallons of paint/stain handled are from the EPA estimates of gallonage that could be used in a single day for each exposure scenario of concern.

[e] Daily dermal exposure (mg/day) = Unit exposure (mg/lb ai) * Appl. rate (lb ai/gal or lb/ft^2) * Gallons or square feet treated.
Absorbed dose (mg/kg/day) = Exposure * dermal absorption factor (3.5%) / body weight (60 kg for developmental endpoint).

f Daily inhalation exposure (mg/day) = [Unit exposure (µg/lb ai)/1,000 µg/mg conversion] * Appl. rate (lb ai/gal or lb/ft^2) * Gallons or square feet treated.
Inhalation dose (mg/kg/day) = Exposure * inhalation absorption factor (100%)/body weight (70 kg)
g MOE [dermal] = NOAEL $_{dermal}$ (10 mg/kg/day) / Absorbed daily dermal dose (mg/kg/day)
h MOE [inhalation] = NOAEL $_{inhalation}$ (0.96 mg/kg/day) / Absorbed daily inhalation dose (mg/kg/day)
"No data" scenarios: refer to Section 2.1.3, "Data Gaps"

Table A-3: Occupational MBC Handlers: Mitigation: Engineering Controls: Short-term and Intermediate-term Dermal and Inhalation Exposure and Risk Estimates

Exposure Scenario (Scenario #)	Dermal Unit Exposure (mg/lb ai)[a]	Inhalation Unit Exposure (µg/lb ai)	Application Rate[b]	Amount Handled[c]	Absorbed Daily Dermal Exposure (mg/kg/day)[d]	Daily Inhalation Exposure (mg/kg/day)[e]	Dermal MOE[f]	Inhalation MOE[g]
Mixer/Loader Exposure								
Adding Paste Formulation (9.9% ai) to Paint at the Manufacturing Process (1a)[h]	0.024	0.083	0.05 lb ai/gallon	4,000 gallons of Paint	2.8-03	2.4E-04	3600	4000
Adding Powdered Formulation (99% ai) to Paint at the Manufacturing Process (1b)[i]	0.021	0.24	0.02 lb ai/gallon		9.8E-04	2.7E-04	10,000	3600
Applicator Exposure								
Applying Paint/Coating Product with a Paint Brush (2)	Not feasible	Not feasible	0.05 lb ai/gallon	5 gallons	Not feasible	Not feasible	Not feasible	Not feasible
Applying Paint/Coating Formulation with an Airless Sprayer (3)	Not feasible	Not feasible	0.125 lb ai/1,000 ft^2	5,600 ft^2	Not feasible	Not feasible	Not feasible	Not feasible

a Dermal unit exposure represents long pants, long sleeved shirt, no gloves; closed mixing/loading. 1a unit exposure derived from PHED closed mixing & loading liquids scenario; 1b exposure derived from wettable powder in water soluble bag (WSB). Both 1a and 1b hand exposure back-calculated using 90% hand protection factor as "no glove" data not available.

b Based on maximum final concentration 0.5% for 99% formulation label, and 0.2% for 9.9% formulation label; it is assumed that the paint density is 10 lb/gallon (the same as the formulation). Therefore 10 lb/gal x 0.5% ai = 0.05 lb ai/gal x 2.5 gal/1,000 ft^2 typical application rate = 0.125 lb/1000 ft^2; assumed house size of 30 ft x 40 ft x 20 ft (2,400 ft^2 living area and 2,800 ft^2 outdoor surface area treated x 2 houses/day).

c Daily gallons of paint/stain handled are from the EPA estimates of gallonage that could be used in a single day for each exposure scenario of concern.

d Daily dermal exposure (mg/day) = Unit exposure (mg/lb ai) * Appl. rate (lb ai/gal or lb/ft^2) * Gallons or square feet treated.
Absorbed daily dose [dermal] = Exposure * dermal absorption factor (3.5 %) / body weight (60 kg for developmental endpoint).

e Daily inhalation exposure (mg/day) = [Unit exposure (µg/lb ai)/1,000 µg/mg conversion] * Appl. rate (lb ai/gal or lb/ft^2) * Gallons or square feet treated.
Absorbed daily dose [inhalation] = Exposure * absorption factor 100 %) / body weight (60 kg for developmental endpoint).

f MOE [dermal] = NOAEL $_{dermal}$ (10 mg/kg/day) / Absorbed daily dermal dose (mg/kg/day)

g MOE [inhalation] = NOAEL $_{inhalation}$ (0.96 mg/kg/day) / Absorbed daily inhalation dose (mg/kg/day)

h Surrogate data from closed liquid mixing and loading (PHED) due to insufficient replicates in CMA database; however, data agree well with PHED closed system data

i Surrogate data from PHED for WP in water-soluble bag

Table A-4a: Baseline Occupational Cancer Risk Estimates for MBC Formulators and Product Applicators

Exposure Scenario (#)	Number of Treatments per year[d]	Lifetime Absorbed Daily Dermal Dose (mg/kg/day)[a]	Lifetime Absorbed Daily Inhalation Dose (mg/kg/day)[b]	Lifetime Absorbed Daily **Total** Dose (mg/kg/day)[c]	Cancer Risk Estimate[e]
Mixer/Loader Cancer Risk Estimates					
Adding Paste (9.9% ai) to Paint at the Manufacturing Process (1a)	50	6.3E-05	9.4E-05	1.6E-04	3.8E-07
Adding Powdered Formulation (99% ai) to Paint at the Manufacturing Process (1b)	50	1.2E-03	8.4E-03	9.6E-03	2.3E-05
Applicator Cancer Risk Estimates					
Applying Ready-to-use Formulation or Paint Product with a Paint Brush (2)	50	1.8E-03	6.8E-05	1.9E-03	4.5E-06
Applying Ready-to-use Paint/Stain Formulation with an Airless Sprayer (3)	50	1.1E-03	5.7E-04	1.7E-03	4.1E-06
Applying Ready-to-use Formulation or Paint Product with a Paint Roller (4)	No data	No data	No data	No data	No data
Applying Ready-to-use Plaster Formulation with Trowel (5)	No data	No data	No data	No data	No data
Applying Ready-to-use Sealant Formulation by Hand (6)	No data	No data	No data	No data	No data
Applying Tree Injection (7)	No data	No data	No data	No data	No data
Loading/Applying Ready-to-use Paint/Coating Product with a Low-Pressure Handwand (8)	50	8.8E-03	7.3E-05	8.9E-03	2.1E-05

[a] Dermal LADD (mg/kg/day) = Absorbed Daily Dose (mg/kg/day)[from Table A1] * adjustment for body weights (60 kg/70 kg)* (number of days per year worked / 365 days per year) * (35 years painting / 70 years lifetime).

[b] Inhalation LADD (mg/kg/day) = Absorbed Daily Dose (mg/kg/day) [from Table A1] * (number of days per year worked / 365 days per year) * (35 years painting / 70 years lifetime).

[c] Total LADD = $ADD_{dermal} + ADD_{inhalation}$

[d] Number of Treatments per year are based on CMA and sources.

[e] Cancer Risk Estimate = Total LADD (mg/kg/day) * (Q_1^*). Where $Q_1^* = 2.39 \times 10^{-3}$ $(mg/kg/day)^{-1}$

"No Data" scenarios: Refer to Section 2.3 Occupational Risk Characterization

Table A-4b: Occupational Cancer Risk Estimates for MBC Formulators and Product Applicators Wearing Chemical Resistant Gloves and Respirator

Exposure Scenario (Scenario #)	Number of Treatments per year[d]	Lifetime Absorbed Daily Dermal Dose (mg/kg/day)[a]	Lifetime Absorbed Daily Inhalation Dose (mg/kg/day)[b]	Total Lifetime Absorbed Daily Dose (mg/kg/day)[c]	Cancer Risk Estimate[e]
Mixer/Loader Cancer Risk Estimates					
Adding Paste (9.9%ai) t o Paint at the Manufacturing Process (1a)	50	6.3E-05	1.9E-05	8.2E-05	2.0E-07
Adding Powdered Formulation (99% ai) to Paint at the Manufacturing Process (1b)	50	1.2E-03	1.7E-03	2.9E-03	6.9E-06
Applicator Cancer Risk Estimates					
Applying Ready-to-use Formulation or Paint Product with a Paint Brush (2)	50	NE	NE	NE	NE
Applying Ready-to-use Paint/Stain Formulation with an Airless Sprayer (3)	50	NE	NE	NE	NE
Applying Ready-to-use Formulation or Paint Product with a Paint Roller (4)	No data	No data	No data	NE	No data
Applying Ready-to-use Plaster Formulation with Trowel (5)	No data	No data	No data	NE	No data
Applying Ready-to-use Sealant Formulation by Hand (6)	No data	No data	No data	NE	No data
Applying Tree Injection (7)	No data	No data	No data	NE	No data
Loading/Applying Ready-to-use Paint/Coating Product with a Low-Pressure Handwand (8)	50	3.7E-05	7.5E-05	1.1E-04	2.6E-07

[a] Dermal LADD (mg/kg/day) = Absorbed Daily Dose (mg/kg/day)[from Table A2] * adjustment for body weights (60 kg/70 kg) * (number of days per year worked / 365 days per year) * (35 years painting / 70 years lifetime).
[b] Inhalation LADD (mg/kg/day) = Absorbed Daily Dose (mg/kg/day) [from Table A2] * (number of days per year worked / 365 days per year) * (35 years painting / 70 years lifetime).
[c] Total LADD = $ADD_{dermal} + ADD_{inhalation}$
[d] Number of Treatments per year are based on CMA and other data.
[e] Cancer Risk Estimate = Total LADD (mg/kg/day) * (Q_1^*). Where $Q_1^* = 2.39 \times 10^{-3}$ $(mg/kg/day)^{-1}$
NE = Not evaluated because MOE greater than 100 or cancer risk less than 10^{-6} with lesser control level.
"No Data" Scenarios: Refer to Section 2.3 Occupational Risk Characterization

Table A-4c: Occupational Cancer Risk Estimates for MBC Formulators and Product Applicators with Engineering Controls Where Feasible

Exposure Scenario (Scenario #)	Number of Treatments per year[d]	Lifetime Absorbed Daily Dermal Dose (mg/kg/day)[a]	Lifetime Absorbed Daily Inhalation Dose (mg/kg/day)[b]	Total Absorbed Daily Dose (mg/kg/day)[c]	Cancer Risk Estimate[e]
Mixer/Loader Cancer Risk Estimates					
Adding Paste (9.9% ai) to Paint at the Manufacturing Process (1a)	50	1.6E-04	1.6E-05	1.8E-04	4.3E-07
Adding Powdered Formulation (99% ai) to Paint at the Manufacturing Process (1b)	50	5.8E-05	1.9E-05	7.6E-05	1.8E-07
Applicator Cancer Risk Estimates					
Applying Ready-to-use Formulation or Paint Product with a Paint Brush (2)	Not feasible				
Applying Ready-to-use Paint/Stain Formulation with an Airless Sprayer (3)	Not feasible				
Applying Ready-to-use Formulation or Paint Product with a Paint Roller (4)	Not feasible				
Applying Ready-to-use Plaster Formulation with Trowel (5)	Not feasible				
Applying Ready-to-use Sealant Formulation by Hand (6)	Not feasible				
Applying Tree Injection (7)	Not required				
Loading/Applying Ready-to-use Paint/Coating Product with a Low-Pressure Handwand (8)	Not feasible / NE				

[a] Dermal LADD (mg/kg/day) = Absorbed Daily Dose (mg/kg/day)[from Table A3]* adjustment for body weights (60 kg/70 kg) * (number of days per year worked / 365 days per year) * (35 years painting / 70 years lifetime).

[b] Inhalation LADD (mg/kg/day) = Absorbed Daily Dose (mg/kg/day) [from Table A3] * (number of days per year worked / 365 days per year) * (35 years painting / 70 years lifetime).

[c] Total LADD = $ADD_{dermal} + ADD_{inhalation}$

[d] Number of Treatments per year are based on HED's best estimate.

[e] Cancer Risk Estimate = Total LADD (mg/kg/day) * (Q_1^*). Where $Q_1^* = 2.39 \times 10^{-3}$ $(mg/kg/day)^{-1}$

Table A-5: Short-term Residential Applicator Dermal and Inhalation Exposures to MBC Formulated Paint & Coatings

Exposure Scenario (Scenario #)	Residential Dermal Unit Exposure (mg/lb ai)[a]	Residential Inhalation Unit Exposure (μg/lb ai)	Application Rate[b]	Amount Handled[c]	Absorbed Dermal Dose (mg/kg/day)[d]	Inhalation Dose (mg/kg/day)[e]	Dermal MOE[f]	Inhalation MOE[g]
Applying Ready-to-Use Paint/Coating Product with a Paint Brush (1)	230	284	0.05 lb ai/gallon	2 gallons	0.013	4.1E-04	750	2400
Applying Ready to - Use Paint/Coating Formulation with an Airless Sprayer (2)	79	830	0.125 lb ai / 1,000 ft^2	2,800 ft^2	0.016	0.0042	620	230
Loading & Applying Ready-to-use Formulation or Paint Product with a Paint Roller (3)	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data
Applying Plaster Formulation with a Trowel (4)	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data
Applying Sealant Formulation (5)	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data
Loading/Applying Ready-to-use Paint/Coating Product with a Low-Pressure Handwand (6)	100	30	0.05 lb ai/ gal	5 gal	0.015	1.1E-04	690	9000

[a] Baseline dermal unit exposure represents short pants, short sleeve shirt, no gloves; from Draft SOPs for Residential Exposure Assessments 12/97

[b] Based on maximum final concentration 0.5% for 99% formulation label, and 0.2% for 9.9% formulation label; it is assumed that the paint density is 10 lb/gallon (the same as the formulation). Therefore 10 lb/gal x 0.5% ai = 0.05 lb ai/gal x 2.5 gal/1,000 ft^2 typical application rate = 0.125 lb/1000 ft^2; assumed house size of 30 ft x 40 ft x 20 ft (2,400 ft^2 living area and 2,800 ft^2 outdoor surface area treated) from Draft SOPs for Residential Exposure Assessments 12/97.

[c] Amounts handled are based on Draft SOPs for Residential Exposure Assessments 12/97: 2 gallons/day; 4 days per year

[d] Exposure (mg/day) = Unit exposure (mg/lb ai) * Appl. rate (lb ai/gal or lb/ft^2) * gallons or square feet treated;

Absorbed daily dose [dermal] = Exposure * dermal absorption factor (3.5%) / body weight (60 kg for developmental endpoint).

e Daily inhalation exposure (mg/day) = [Unit exposure (μg/lb ai)/1,000 μg/mg conversion] * Appl. rate (lb ai/gal or lb/ft^2) * gallons or square feet treated; Absorbed daily dose [inhalation] = Exposure * inhalation absorption factor (100%) / body weight (70 kg for developmental endpoint).

f MOE [dermal] = $NOAEL_{dermal}$ (10 mg/kg/day) / Absorbed daily dermal dose (mg/kg/day)

g MOE [inhalation] = $NOAEL_{inhalation}$ (0.96 mg/kg/day) / Absorbed daily inhalation dose (mg/kg/day)

"No data" scenarios: refer to Section 3.1.4

Table A-6: Cancer Risk Estimates for Residential Handlers of MBC-Containing Formulations

Exposure Scenario (Scenario #)	Lifetime Absorbed Daily Dermal Dose (mg/kg/day)[a]	Lifetime Absorbed Daily Inhalation Dose (mg/kg/day)[b]	Total Lifetime Absorbed Daily Dose (mg/kg/day)[c]	Number of Treatments per year[d]	**Total** Cancer Risk Estimate[e]
Applying Ready-to-use Formulation or Paint Product with a Paint Brush (1)	8.7E-05	3.2E-06	9.0E-05	4 [rooms]	2.2E-07
Applying Ready-to-use Paint/Stain Formulation with an Airless Sprayer (2)	2.7E-05	8.2E-06	3.5E-05	1 [1 house]	8.4E-08
Applying Ready-to-use Formulation or Paint Product with a Paint Roller (3)	No data	No data	No data	No data	No data
Applying Ready-to-use Plaster Formulation with Trowel (4)	No data	No data	No data	No data	No data
Applying Ready-to-use Sealant Formulation by Hand (5)	No data	No data	No data	No data	No data
Applying Ready-to-Use Liquid Sealant using Handwand (6)	2.5E-05	2.2E-07	2.5E-05	5 gallons	6.0E-08

[a] Dermal LADD (mg/kg/day) = Absorbed Daily Dose (mg/kg/day)[from Table A5] * adjustment for body weights (60 kg/70 kg) * (number of days per year worked / 365 days per year) * (50 years painting / 70 years lifetime).

[b] Inhalation LADD (mg/kg/day) = Absorbed Daily Dose (mg/kg/day) [from Table A5] * (number of days per year worked / 365 days per year) * (50 years painting / 70 years lifetime).

[c] Total LADD = $ADD_{dermal} + ADD_{inhalation}$

[d] Number of Treatments per year are based on HED's best estimate.

[e] Cancer Risk Estimate = Total LADD (mg/kg/day) * (Q_1^*). Where $Q_1^* = 2.39 \times 10^{-3}$ $(mg/kg/day)^{-1}$

"No data" scenarios: Refer to Section 3.1.4

Table A-7: Exposure Scenario Descriptions for the Use of MBC

Exposure Scenario (Number)	Data Source	Standard Assumptions (8-hr work day)[a,b]	Comments[c]
Mixer/Loader Descriptors			
Adding Paste (Liquid) Formulation to the Product at the Manufacturing Process (1a)	PHED V1.1	4,000 gallons of paint treated	**Baseline:** (Single layer with gloves) Dermal = 72 to 122 replicates, AB grade. Hand = 53 replicates, AB grade. **PPE**: 50% PF for coveralls for body. Engineering Controls: (Closed Mixing/loading): No-glove exposure back-calculated using a 90% PF from gloved data. Dermal = 16 to 22 replicates. Gloved hand replicates = 31. Low confidence due to back-calculation from high-confidence data. **PHED** data used for baseline and PPE, a 5-fold Protection Factor (PF) was used for a dust/mist respirator. Inhalation: Replicates = 85, AB grade. High confidence (Open loading). Replicates = 27, AB grade, high confidence (Closed loading).
Adding Powder Formulation to Product at the Manufacturing Process (1b)	PHED V1.1 Surrogate = Wettable Powder	4,000 gallons of paint treated	**Baseline:** (Single layer, gloved). Dermal replicates = 22 to 45, ABC Grade. Hand replicates = 24. Medium confidence. Engineering Controls: (Wettable powder in soluble bag) Dermal replicates 6-15, AB grade. Hand replicates = 5, AB grade. Low confidence due to low replicate numbers and largely non-detects. PPE: 50% PF for coveralls for body, a 5-fold PF was used for a dust/mist respirator. Inhalation: Replicates = 44, ABC grade, medium confidence (Open loading). Replicates = 15, all grade, low confidence (WSB)
Applicator Descriptors			
Applying Ready-to-use Coating Formulation with a Paint Brush (2)	PHED V 1.1	(R) 2 gallons (O) 5 gallons	**Baseline and PPE:** Hands, dermal, and inhalation = A, B, C grades. Hands = 15 replicates; dermal = 15 replicates; inhalation = 15 replicates. Medium confidence in dermal and inhalation data. A 50 percent PF representing coveralls and a 90 percent PF for chemical resistant gloves were applied to the baseline data to determine the PPE exposure scenario.(Occupational only)

Exposure Scenario (Number)	Data Source	Standard Assumptions (8-hr work day)[a,b]	Comments[c]
Applying Ready-to-use Coating Formulation with an Airless Sprayer (3)	PHED V 1.1	(R) 2,800 ft^2 (O) 5,600 ft^2	**Baseline and PPE :** Hands and dermal acceptable grade (B); inhalation C grade. Hands = 15 replicates; dermal = 15 replicates; inhalation = 15 replicates. High confidence in dermal data and medium confidence for inhalation data. A 50 percent PF representing coveralls and a 90 percent PF for chemical resistant gloves were applied to the baseline data to determine the PPE exposure scenario.(Occupational only)
Applying Ready-to-use Coating with a Paint Roller (4)	No data	No data	No data; see Sections 2.3 and 3.3 in text
Applying Treated Plaster with a Trowel (5)	No data	No data	No data; see Sections 2.3 and 3.3 in text
Applying Treated Sealant by Hand (6)	No data	No data	No data; see Sections 2.3 and 3.3 in text
Applying Ready-to-use Formulation as a Tree Injection (7)	No data	No data	No data; see Section 2.3 in text; negligible exposure expected
Loading and Applying Ready-to-use Liquid Sealant with Low Pressure Handwand (8 - O) (6 - R)	PHED v. 1.1	(O) 50 gallons (R) 5 gallons	Baseline (R): (Shorts and short-sleeved shirt) Dermal replicates 79 to 80, A, B, and C grade. Hand replicates = 70, all grade. Low confidence due to low hand grades used. Baseline (O): (Single layer, no gloves): Dermal replicates = 9 to 80, ABC grade. Hand replicates = 70, all grade. Low confidence due to inadequate replicate number and low hand grades used. Single layer, gloves (O): Dermal replicates = 9 to 80, ABC grade. Hand replicates = 10, all grade. Low confidence due to inadequate replicate number; gloved hand estimates based on nearly all non-detects. Inhalation: 80 replicates, ABC grade, medium confidence.

(R) = Residential
(O) = Occupational Handler

[a] Standard Assumptions based on an 8-hour work day as estimated by HED.

[b] Chemical Manufacturers Association, Antimicrobial Exposure Assessment Study. Reviewed by S. Mostaghimi and W. Dang, EPA RASSB, Antimicrobials Division.

[c] "Best Available" grades are defined by EPA SOP for meeting Subdivision U Guidelines. Best available grades are assigned as follows: matrices with grades A and B data and a minimum of 15 replicates; if not available, then grades A, B and C data and a minimum of 15 replicates; if not available, then all data regardless of the quality and number of replicates. Data confidence are assigned as follows:
High = grades A and B and 15 or more replicates per body part
Medium = grades A, B, and C and 15 or more replicates per body part
Low = grades A, B, C, D and E or any combination of grades with less than 15 replicates

Table A-8. Scenarios and Input Parameters for *MCCEM*										
Use Scenario	**House Type & Season**	**Air Exchange Rate (xch/hr)**	**Chamber Type (Number Zones)**	**Model Type**	**Calculation Duration (days)**	**Emission Type**	**Emission Rate**	**Product Use Scenario**	**Room of Use**	***MCCEM* Decay Rate**
Paints/ Coatings	Summer	0.18	Dual (2)	Long-Term	365	Chinn Evaporation	Chinn Rate 2.2E-07 g/hr	Bathroom Paint	Bathroom	0.00

A 2-zone model was used to predict painting one room, i.e., a bathroom, and assuming the resident would be exposed to the airborne concentration of MBC vapor in the remainder of the home. The model results are listed in the text, Section 3.2.1.

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Chemical:	**Carbamic acid, 1H-benzimidazole-2-yl-, m; Benomyl; Thiophanate-methyl**
PC Code:	**128872; 099101; 102001**
HED File Code	**12000 Exposure Reviews**
Memo Date:	**03/21/2001**
File ID:	**DPD273465**
Accession Number:	**412-02-0010**

HED Records Reference Center
01/04/2002